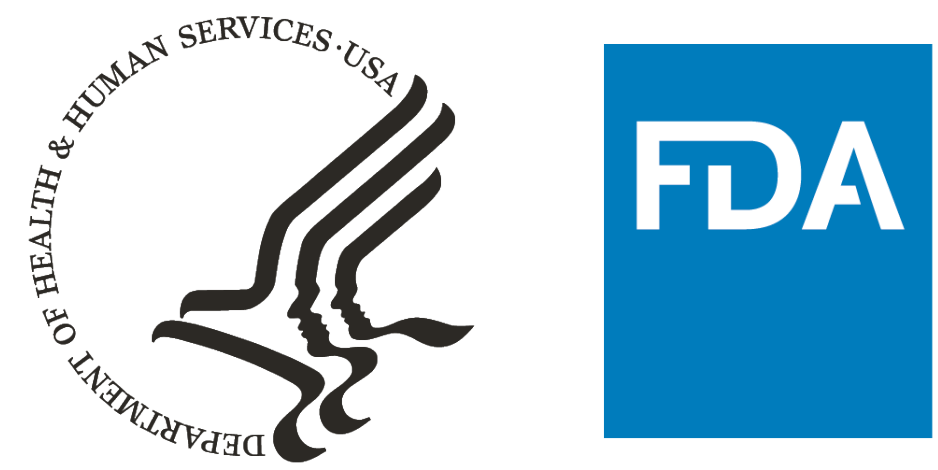# OCS Analysis Studio 2.0:
Cutting-Edge Tools for Detecting Safety Signals and Crafting Review-Ready Tables and Figures

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Abstract

OCS Analysis Studio offers a set of fit-for-use, exploratory and flexible analysis tools for the clinical review process. These tools include the creation of tables and figures for application review, as well as data visualizations. Among the most used tools are Safety Explorer, Custom Table Builder, and Hepatic Explorer. These tools feature an intuitive and consistent user interfaces, empowering users to quickly create customized tabular and graphical analyses that conform to OND standard review guidance. Through a connection to the OCS Data Central service, users can utilize the Analysis Studio suite without the need for file uploads, by querying the specific application and studies to explore. Real-time interactivity allows users to rapidly interrogate signals of interest. These tools also allow for collaborative work, providing auditability and replicability through URL sharing and bookmarking. These tools have the capacity to export data outputs into Microsoft formats (xlsx and docx), allowing for easy integration into review documents. Analysis Studio tools are deployed in a cloud environment for enhanced speed, reliability, and diagnostics. Since July 2023, the site has over 2,000 analysis sessions performed by more than 500 unique users, supporting numerous clinical reviews and analyses.

Introduction

[2018] *Launched OCS Analysis Studio*

[2021] *Migrated OCS Analysis Studio to FDA RAPID Cloud*

[2024] *Releasing OCS Analysis Studio 2.0 in CDERone*

Key Benefits of Analysis Studio 2.0

- URL Bookmarking – easily reproduce and share analyses
- Direct connection to *OCS Data Central* service for data upload
- Architecture redesign for enterprise performance and scaling
- New potential for standard analysis automation
- Enhanced user metrics
- **8 tools in total:** Safety Explorer, Custom Table Builder, Kidney Function, Hepatic Explorer, Shift Table, Listing Table, Custom MedDRA Query (CMQ) Builder, Scatterplot Grid

Materials and methods

The *OCS Analysis Studio 2.0* tools are built upon an architecture designed for stability and reproducibility. The new architecture leverages Microsoft .NET for the user interface and couples to a statistical computing engine built in R. The tool suite is containerized with Docker and has been hosted on Kubernetes-based servers on OCS platforms.
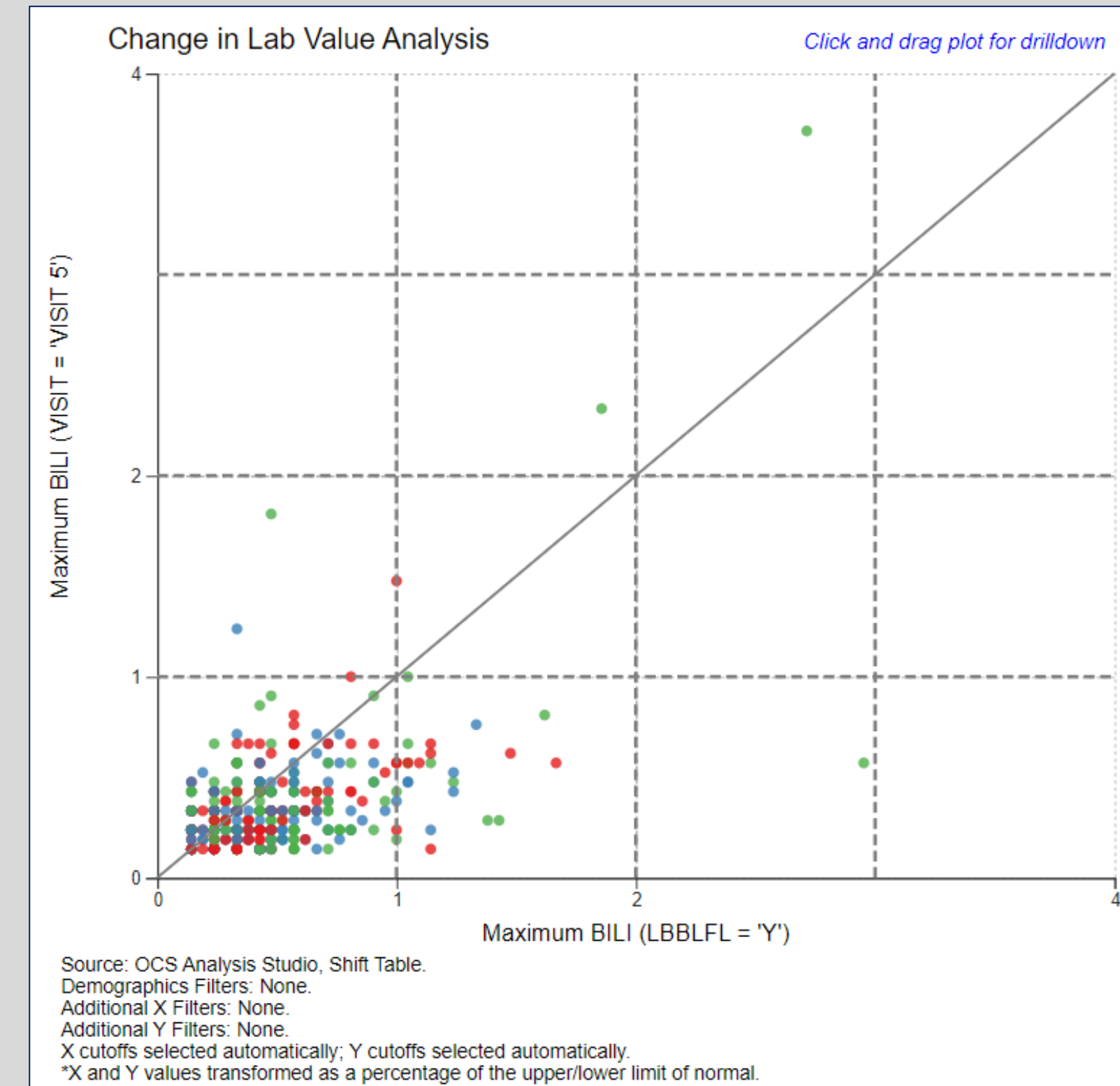
Results and discussion

Samples of *OCS Analysis Studio 2.0* Tool Outputs

SHIFT TABLE

The Shift Table Tool provides insight into the progression of study subjects' lab readings over time. Summary visualizations include a scatterplot figure and shift table organized by treatment group.

HEPATIC EXPLORER

This tool produces the industry-standard Drug-Induced Liver Injury (DILI) plot, with interactive subject-level selections allowing users to identify elevated on-treatment liver tests and assess candidates for hepatotoxicity.
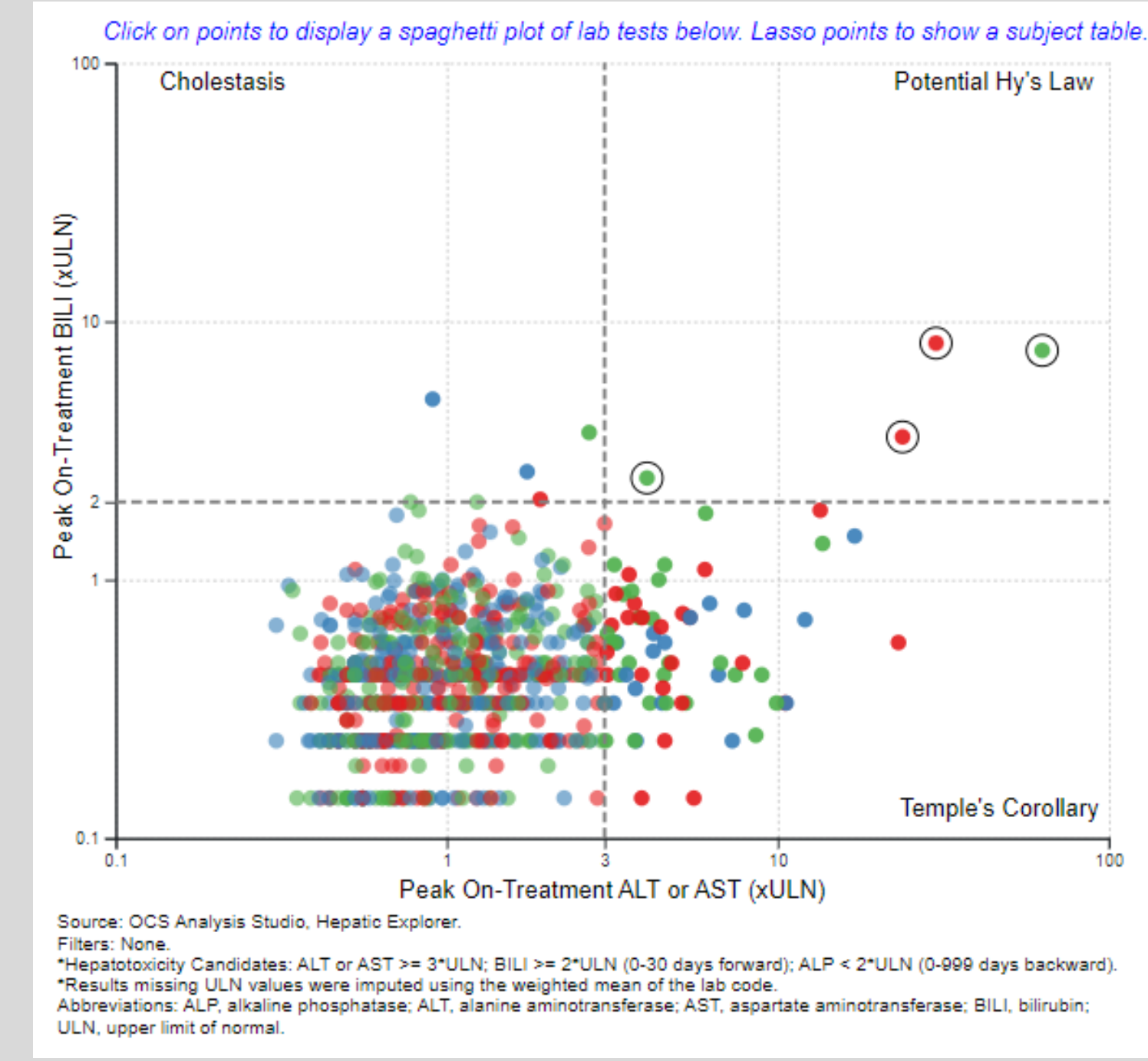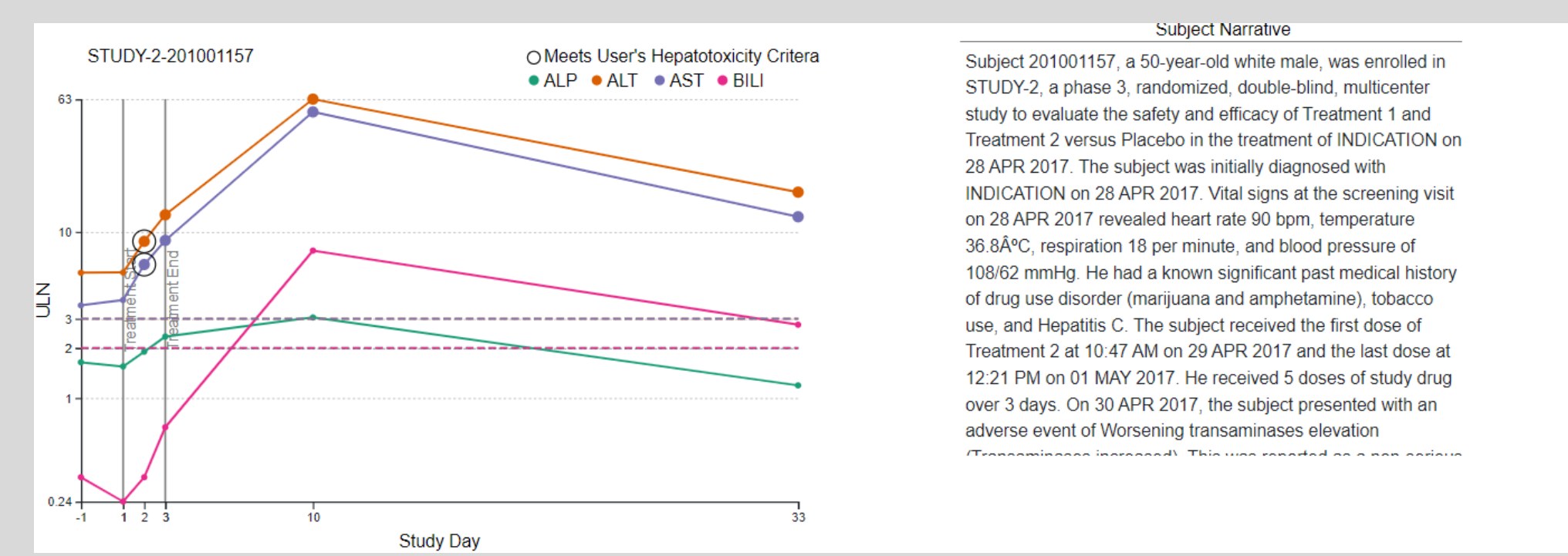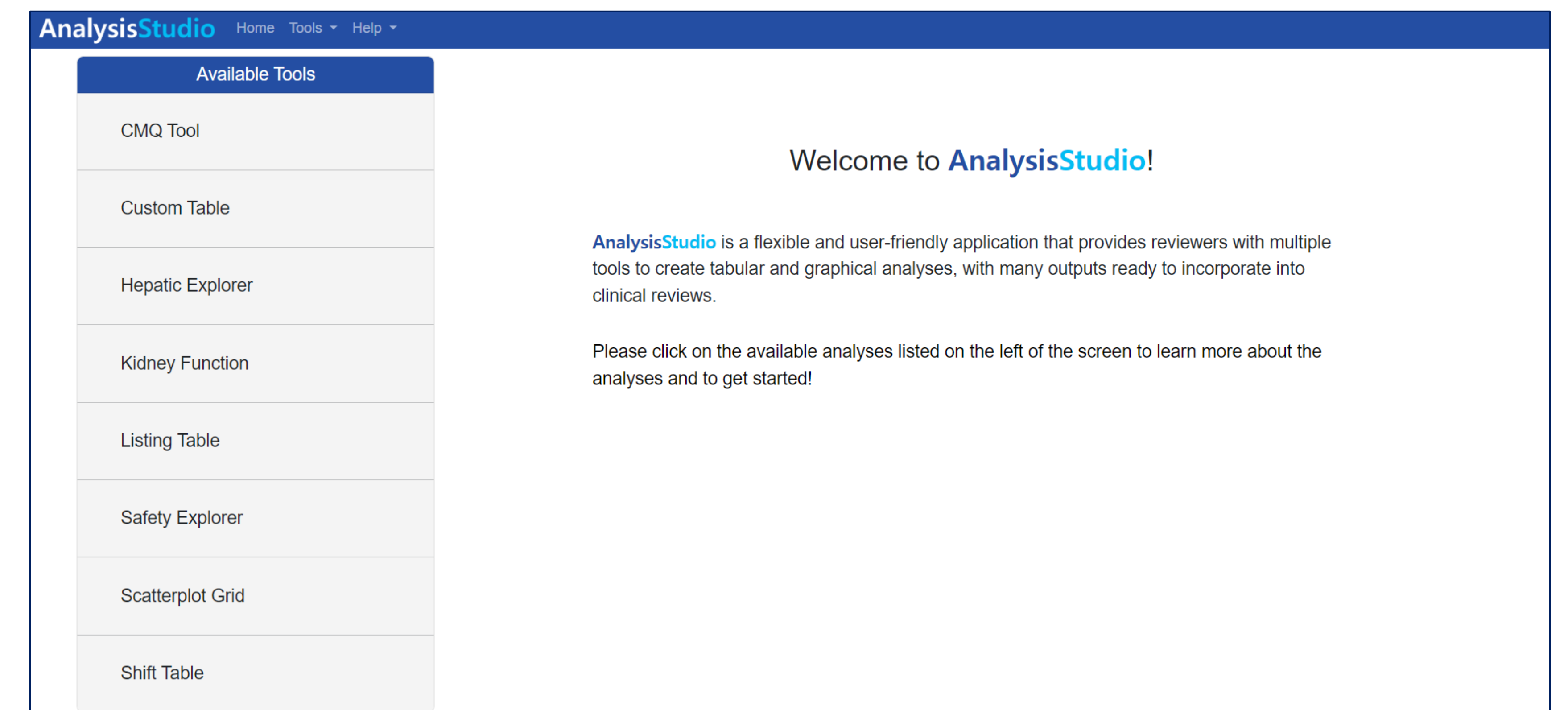

SAFETY EXPLORER

Creates four standard summary tables of Treatment-Emergent Adverse Events (TEAEs):

- Summary of TEAEs
- Summary of Serious TEAEs
- Summary of TEAEs by Severity-Toxicity
- Summary of TEAEs Leading to Discontinuation

Provides users access to Risk Estimators and Forest Plots, column-level sorting, organization of tables by Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class and/or Preferred Term, optional display of tables based on user-uploaded Custom MedDRA Query (CMQ) Files, and filtering table by AE incidence percentage.

OCS Analysis Studio 2.0 Home Page

Connecting with the data hub - *OCS Data Central*

- Direct connection to *OCS Data Central* repository
- Automated retrieval of all available Application and Study datasets
- Automatic upload of all required datasets
- Support for SDTM and ADaM data
- Support for RDS, XPT, SAS7BDAT formats

Conclusion

OCS Analysis Studio contains a set of intuitive and powerful exploratory tools that can be leveraged to aid clinical review through a range of general and specialized analyses. The new Analysis Studio 2.0 tool suite will reside in the CDER One Analytics platform to provide CDER users with an enterprise-grade analysis experience. Users may access new features that enable rapid reproduction of analyses, enhancements to data ingestion, and greater overall stability. There are additional enhancement in pipeline for Analysis Studio future versions where it can perform analysis beyond clinical review (e.g pharmacology, nonclinical)